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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/587,184	08/31/2006	Pierre J-M. Riviere	15041.0006USWO	6577

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EXAMINER	
XIE, XIAOZHEN	
ART UNIT	PAPER NUMBER
1646	
MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,184	RIVIERE ET AL.	
	Examiner	Art Unit	
	XIAOZHEN XIE	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 December 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 3-23* is/are pending in the application.

4a) Of the above claim(s) *5 and 13-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3,4,6-12 and 21-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 July 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114.

Applicant's amendment of the claims filed on 3 December 2009 has been entered. Applicant's remarks filed 3 December 2009 are acknowledged.

Claim 2 is cancelled. Claims 1 and 3-23 are pending. Claims 13-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention. Claim 5, which is directed to PTHrP or an analogue thereof, is withdrawn from further consideration as being drawn to a nonelected species. Claims 1, 3, 4, 6-12 and 21-23 are under examination to the extent they read on the elected species: (1) a PTH receptor agonist which comprises an activation domain comprising an amino acid sequence of SVSEIQL (aa 1-7 of SEQ ID NO: 1) and a receptor binding domain comprising an amino acid sequence of LRKKLQDVHNF (aa 24-34 of SEQ ID NO: 1); and (2) a PTH receptor agonist of SEQ ID NO: 1.

Claim Objections Withdrawn

The objections to claim 3 for uses an acronym ("PTH") without first defining what they represent in the independent claims is withdrawn in response to Applicant's amendment of the claims.

Claim Objections/Rejections Maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 4, 6, 7, 10-12 and 21-23 are rejected under 35 U.S.C. 102(b), as being anticipated by Hock (WO 01/21198, International Publication Date 29 March 2001), as evidenced by Mercadante (Pain, 1997, Vol. 69:1-18).

Hock teaches administration of a parathyroid hormone, such as rhPTH(1-34) (also known as teriparatide), into patients that have cancer established and growing in bone, including metastasized bone cancer from breast, prostate and lung cancer (pp. 8, lines 15-30; pp. 15, lines 9-14). rhPTH(1-34) has the amino acid sequence set forth in SEQ ID NO: 1, and comprises the activation domain (amino acids 1-6 of SEQ ID NO: 1), and the receptor binding domain (amino acids 24-34 of SEQ ID NO: 1). The patient population in the Hock disclosure, i.e., those have cancer established and growing in bone, meets the limitation of "*an individual suffering from pain associated with the growth of bone metastasized cancer or bone-originated cancer*", because pain is commonly present in bone cancer patients, such is evidenced by Mercadante.

Mercadante teaches that the presence of bone metastases predicts the presence of pain and is the most common cause of cancer-related pain (see Abstract). Hock teaches that the hormone is administered in a daily dose in the range of at least about 15-40 μg (pp. 6, lines 20-23). Thus, Hock anticipates the instant claims.

In the remarks received on 3 December 2009, Applicant argues that amended claim 1 recites "A method of ameliorating pain in an individual suffering from pain"; and the patient population for the presently claimed method is different from that disclosed by the Hock reference. Applicant argues that the Hock reference does not include the word "pain" and relates to reducing the risk of certain cancers, not treating patients suffering from cancer. Applicant argues that a reference that does not include the word "pain" cannot teach or suggest a method of ameliorating pain.

Applicant's argument has been fully considered but has not been found to be persuasive.

Amended claim 1 recites "A method of ameliorating pain in an individual suffering from pain associated with the growth of bone metastasized cancer or bone-originated cancer ". As stated above, Hock teaches administration of a parathyroid hormone, such as rhPTH(1-34), into patients that have cancer established and growing in bone. Pain is commonly present in bone cancer patients as evidenced by Mercadante. Thus, the patient population disclosed in the Hock reference overlaps from that of the presently claimed method.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 8 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hock (WO 01/21198), in view of McKenna et al. (J. Bone Joint Surg. Am., 1966, 48:1-26).

Hock teaches as set forth above. Hock further teaches that the method can aid maintenance and rebuilding of the bone in a bone cancer patient, and can reduce the risk of fracture in such bone (pp. 8, lines 15-30). Hock, however, does not teach that the individual has bone-originated cancer, e.g., sarcoma (claims 8, 9).

McKenna et al. analyzed sarcomas of osteogenic series in 552 cases with primary or secondary osteogenic sarcoma, and found that the symptoms of the bone cancer in these patients include pathological fracture and pain (pp. 8, section "Signs and Symptoms").

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to combine the teachings of Hock with those of McKenna et al., to use a parathyroid hormone to reduce the risk of fracture in cancerous bone resulted from the growth of osteosarcoma. One of ordinary skill in the art would have been motivated to do so, because Hock teaches that a parathyroid hormone can reduce the risk of fracture of a cancerous bone in patients with metastasized bone cancer, and can aid maintenance and rebuilding of such bone, and McKenna et al. further teaches

that pathological fracture is one of the primary clinical symptoms occurring in primary and secondary osteosarcoma patients. Therefore, the combined teachings provide a reasonable expectation of successfully reducing the risk of pathological fracture, thereby ameliorating the damage in these patients.

In the remarks received on 3 December 2009, Applicant argues that the Hock reference does not include the word "pain" and relates to reducing the risk of certain cancers, e.g., breast carcinoma, skin carcinoma, bladder carcinoma, and gastric carcinoma. Applicant argues that the McKenna et al. reference discusses bone cancers and is silent regarding parathyroid hormone. Applicant argues that these references relate to different disorders and nothing in them suggests combining them; further, a reference that is silent regarding pain combined with a reference that is silent regarding parathyroid hormone receptor agonists cannot teach or suggest a method of ameliorating pain that includes administering a parathyroid hormone receptor agonist.

Applicant's argument has been fully considered but has not been found to be persuasive.

Although Hock is silent regarding pain, Hock, however, teaches that a parathyroid hormone can reduce the risk of fracture in cancerous bone in a patient with metastasized bone cancer, and can aid maintenance and rebuilding of such bone. Although McKenna et al. is silent regarding parathyroid hormone, the reference, however, teaches that pathological fracture is one of the primary clinical symptoms occurring in primary and secondary osteosarcoma patients. Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made

to modify the method taught by Hock, in view of the teachings by McKenna et al., to administer a parathyroid hormone into an osteosarcoma patient, because by doing so, it can reduce the risk of fracture in cancerous bone, and can aid maintenance and rebuilding of such bone. Further, MPEP states that: the reason or motivation to modify the reference may often suggest what the inventor has done, but for a different purpose or to solve a different problem. It is not necessary that the prior art suggest the combination to achieve the same advantage or result discovered by applicant. See, e.g., In re Kahn, 441 F.3d 977, 987, 78 USPQ2d 1329, 1336 (Fed.Cir. 2006).

Claim Objections

Claim 21 remains objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 21 recites wherein the activation domain is selected from the group consisting of amino acids SVSEIQ (aa 1-6 of SEQ ID NO: 1), which is 6 amino acid residues in-length. However, claim 1, to which claim 21 depends from, recites the activation domain comprising the amino acids sequence X_1-V-S-E-X_2-Q-X_3, which is 7 amino acid residues in-length.

Applicant indicates that the claim has been amended to overcome the objection. However, claim 21, as amended, still recites wherein the activation domain is selected from the group consisting of amino acids SVSEIQ (aa 1-6 of SEQ ID NO: 1) (a sequence with 6 amino acids), which fails to further limit the previous claim 1 that

recites an activation domain comprising amino acids sequence X_1-V-S-E-X_2-Q-X_3 (a sequence with 7 amino acids).

Conclusion

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Xiaozhen Xie whose telephone number is 571-272-5569. The examiner can normally be reached on M-F, 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol, Ph.D. can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Xiaozhen Xie/
Xiaozhen Xie, Ph.D.
May 14, 2010